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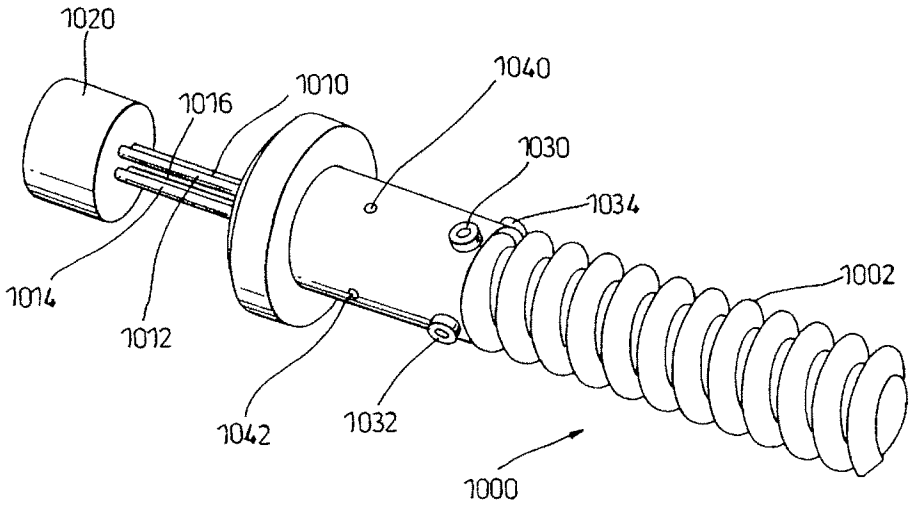
[Continued on next page]

(54) Title: STERILISATION DEVICE



(57) Abstract: A female sterilisation device comprising a plug (100) for occluding a fallopian tube, the plug being held in position

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Sterilisation Device

The present invention relates to sterilisation devices and more particularly to devices which can be used to occlude the fallopian tube for the purposes of female sterilisation.

Known contraceptive devices comprise sterilisation clips, an example of which is the Filshie clip which is used to clip onto and to occlude the fallopian tube. The application of these clips requires laparoscopic surgical techniques and once occluded a further fairly complex surgical operation is necessary to reconnect the tubes should there be a need to reverse the operation.

An alternative solution is the use of pre-formed plugs but many previous techniques have been abandoned because of the high failure rate which is considered unacceptable in any sterilisation technique.

An advantage of using pre-formed plugs is that they may be removable in certain circumstances at a future time to reverse the sterilisation but the possibility of future removal means that the plugs may under certain circumstances become dislodged, leading to failure.

Various attempts have been made to obviate this problem and in particular WO97/12569 to Adam Laszlo Magos proposed use of coarse external screw thread means to anchor the plugs.

Though partially solving the problem this solution still has an unacceptable failure rate.

A further possible solution may be to manufacture each plug from bio-compatible material which could possibly form a permanent plug. Again a problem here is that removal will become extremely difficult once the plug has been in position for any period of time.

A further solution has been proposed by Rudolph et al in US 3,858,571 in which an inert cornual plug is provided with wire anchoring means. This design however is again unsatisfactory resulting in a substantial possibility of failure which is unacceptable in this type of device.

The present invention provides a solution to the above problems.

The present invention provides a sterilisation device comprising a plug which is capable of occluding a fallopian tube;
said plug comprising a generally elongate cylinder said generally elongate cylinder including one or more internal conduit means for entry of one or more suture coils to effect engagement of the plug within the fallopian tube, said suture coils forming a re-entrant loop to effect secure anchoring of the sterilisation device.

Preferably said generally elongate cylindrical shape comprises an outer surface and first and second end surfaces.

Preferably said plug comprises at least three internal conduit means.

Preferably each internal conduit means comprises a shaped passageway with first and second orifices respectively connecting said first end surface with said outer surface.

Preferably said passageway connects with said outer surface of said plug at a position nearer to said first end of said plug than said second end.

This feature will ensure that said suture passes into the more muscular part of the body providing a more secure fixture.

Preferably each said suture comprises a length of surgical wire, said wire having memory characteristics such that when said wire is inserted into said internal conduit means, via said first orifice and passed out of said second orifice, said wire will form a shaped suture providing fixture means to fix said plug to said fallopian tube.

In an alternative embodiment the sutures comprise wires which are pre-shaped to a re-entrant loop shape but are constrained within a suitable structure prior to the sterilisation device being placed in position in the fallopian tube.

Said plug is also preferably provided at said first end surface with handle means enabling said plug to be gripped by an applicator.

The present invention also provides an applicator for insertion of said plug into a fallopian tube, said applicator including means for gripping said handle of said plug to insert said plug into a fallopian tube and including means for moving said one or more sutures through said internal conduit means to emerge from said second orifice to engage with said fallopian tube when said plug is positioned to occlude said fallopian tube.

Preferably each said suture means is provided with anchor means at said end of said suture adjacent to said first orifice, said anchor means

preventing said suture from being further pulled through said internal conduit means.

Preferably said anchor means is shaped to be able to be gripped by extractor tool means to enable each said suture to be removed from said plug thereby enabling said plug to be removed from said fallopian tube to reverse the sterilisation procedure.

Preferably each said suture describes a generally circular path on exiting from said second orifice.

Preferably said plug is provided with one or more surface receptor features, each of which is positioned proximate to each second orifice, said surface receptor features being formed to receive the end of a suture to securely locate the said end of each suture.

In a preferred embodiment the plug may have one or more surface protrusions to effect initial location of said plug in said fallopian tube prior to engagement of said sutures which effect more permanent engagement.

Preferably said surface protrusions may comprise external screw thread means to effect positioning of said sterilisation device within said fallopian tube prior to engagement of said suture coils with said fallopian tube.

Embodiments of the present invention will now be described with reference to the accompanying drawings in which:-

Figure 1 shows a prior art contraceptive device illustrating an applicator and a contraceptive plug, its insertion into the uterine cavity and the final position of the plug devices in the proximal tubal ostia;

Figure 2 shows a plug according to the present invention in longitudinal cross-section illustrating the permanent fixing means provided by sutures;

Figure 3 shows a detail of the plug of Figure 2 in end elevation;

Figure 4 shows a cross sectional view of the plug of Figure 3 in cross-section on line A-A illustrates the internal conduits and first and second orifices;

Figures 5a to 5c illustrate the positioning of the suture to effect permanent fixing of the plug into the tubal ostia;

Figure 6 illustrates diagrammatically an applicator for insertion of said plug and including means for effecting movement of the sutures through the internal conduits;

Figure 7 shows a perspective view of an alternative embodiment of the sterilisation device of the present invention in an initial position prior to insertion into a fallopian tube;

Figure 8 shows the device of Figure 7 in an intermediate position illustrating the initial emergence of the sutures from the main body of the device;

Figure 9 shows the device of Figure 7 in a final position illustrating the re-entrant nature of the sutures in this position; and

Figure 10 is a longitudinal cross sectional view of the device of Figure 9.

With reference now to the drawings, Figure 1 shows diagrammatically a known system for female sterilisation.

Two plugs 10 are respectively inserted into each fallopian tube 20 to effect occlusion thereof by means of a suitable applicator or tool 30.

In accordance with the prior art PCT published patent application WO97/12569 these plugs are provided with screw thread means for secure attachment but this design has been found to give an unsatisfactory failure rate.

An alternative design is disclosed in US 3,858,571 in which a cornual plug of conical shape with wire anchoring means is shown. The design is not successful because the plug is cone shaped which shape although being suitable for entry into the fallopian tube is not conducive to being retained therein. Additionally the wire anchors protrude (see Figure 4) into the fallopian tube at best at an orthogonal direction with respect to the central elongate axis of the cone and this renders the plug liable to be torn out of the fallopian tube because this anchoring in combination with the conical shape is not secure.

In contrast the plug of the present invention comprises an elongate cylinder, preferably with external screw thread means for initial anchoring and sutures which form re-entrant loops thus providing extremely secure anchoring of the plugs.

In accordance with the present invention a new and improved design of plug 100 is diagrammatically shown in Figure 2 in partial cross section to illustrate the various features.

The plug 100 comprises a generally cylindrical elongate solid plug of plastics material suitable for use as a contraceptive device.

The plug may be provided with serrations or surface protrusions 102, 104, shown dotted to assist in initial retention of the plug when inserted. An example of these is shown in the preferred embodiment of Figures 7 to 10.

Permanent fixing means for the plug is provided by one or more sutures 106 which pass through shaped internal conduits 108 which have a first orifice 110 for entry of a suture 106 and a second orifice 112 for exit of the suture 106. These sutures in their final positions form re-entrant loops as shown in Figure 2 and Figure 9 providing secure anchoring of the plug rendering it virtually impossible for the plug to be accidentally dislodged.

The first orifice 110 is on the end surface 114 of plug 110 and the second orifice is on the surface 116 of the generally cylindrical body of plug 100.

The surface 116 is also preferably provided with surface receptor features 118 which as shown are designed to receive the loose ends of the sutures 106.

The sutures 106 may be made from a memory retentive material which may be nitinol (Nickel Titanium alloy) and when not constrained and when the material is at body temperature these sutures curl up to the shape shown in Figure 2. In so doing they exit orifice 112 they engage with the fallopian tube and interlock the plug permanently into position by forming re-entrant loops as shown.

Each suture 106 is provided with an anchor means which is shown in the form of a turned over end 1062. This could be pre-formed into the suture or could be formed by virtue of the retentive memory of the material.

The anchor means 1062 performs two separate functions. Firstly it prevents suture 106 from being pulled through the internal conduit 108 thereby providing a secure fixing for plug 100.

Secondly with the assistance of a suitable tool (not shown) the end 1062 can be gripped and the sutures can be withdrawn enabling the sterilisation procedure to be reversed.

With reference now to Figure 3, the plug preferably has three conduits 108 and is provided with gripping means 124 (shown dotted in Figure 4) to enable the plug to be gripped either during insertion or for removal.

With reference to Figure 4 the plug is shown in cross section on line A-A of Figure 3 without sutures for ease of viewing.

Preferably the exit orifices 112 are nearer to the end surface 110 than the other end 126 so that the sutures exit at a point where the tubal ostia is more muscular thereby ensuring a firmer fixture.

With reference to Figures 5a to 5c, these show the progressive insertion of the suture through the internal guiding conduits (only one shown for ease of drawing). This illustrates the constrainment of the suture in a relatively straight line through the conduit and then the effect of the retentive memory feature which assisted by the shaped end of the conduit near to the orifice 112 causes the suture to effect a circular motion effecting closure of the suture as shown in Figure 5c.

A suitable applicator 200 is shown in Figure 6 with a detailed end section shown in Figure 6a.

The applicator 200 comprises a handle 202 with a lever 204 and a barrel 206 which holds a single plug 100 shown dotted.

With reference to Figure 6a the end of barrel 206 is shown in cross section.

The barrel comprises an inner 210 and an outer 212 cylinder arrangement, the inner cylinder 210 comprising a double cylinder 2102, 2104 with a piston arrangement 214 which is operated by lever 204 to move the piston in the direction of arrow 216.

The sutures 106 are loaded into the space within the double cylinder 2102, 2104 and the suture is moved into conduit means 108 by the movement of piston means 214 in the direction of arrow 216 until in the position shown in Figure 2 wherein the anchor means 1062 prevents further movement.

It will be necessary to restrain suture 106 from sideways movement within dual cylinders 2102, 2104 and this can be provided by suitable guides with piston 214 not being continuous around the whole of cylinder 210.

The contraceptive device of the present invention is therefore permanently fixed by the sutures 106 with no real possibility of being dislodged in any normal manner.

However by removal of sutures 106 via the internal conduits 108 the plug can be released and then removed enabling reversal of the sterilisation procedure.

An alternative preferred embodiment is shown in Figures 7 to 10. The plug 1000 comprises a generally elongate cylindrical body, which is provided with a screw thread 1002 which enables the plug to be screwed into position in the fallopian tube thus providing an initial anchoring for the plug.

The plug is provided with internal conduit means 1004, 1006, 1007, 1008 (only two shown) shown in Figure 10 through which four suture anchoring devices 1010, 1012, 1014, 1016 pass.

The suture devices 1010, 1012, 1014, 1016 may comprise nitonol material or alternatively since they are constrained at their ends by a securing block 1020 and within the internal conduits 1004, 1006 they may be made from stainless steel which has been pre-shaped but is constrained to be straight prior to emergence from the generally elongate body.

The generally elongate cylindrical body comprises four outlet orifices 1030, 1032, 1034, 1036 (only three shown) through which the sutures pass as illustrated in Figure 8.

In a specific embodiment the generally cylindrical elongate body further comprises four surface receptor features 1040, 1042, 1044, 1046 (only two shown in Figure 7) which are designed to accept the ends of the sutures 1010, 1012, 1014, 1016 when fully emerged from the cylindrical block as shown in Figure 9.

As shown in the sequence of Figures 7 to 9 the sutures are pushed out of the orifices 1004, 1006, 1007, 1008 by pressure on block 1020 by suitable applicator means similar to the applicator shown in Figure 6.

The sutures 1010, 1012, 1014, 1016 can be retracted by pulling backwards on block 1020 against collar 1040 to provide a first partial release of the plug. The plug can then be unscrewed in a reverse rotational procedure thereby re-opening the fallopian tube.

It may be seen that the plug provides a sterilisation device which is almost impossible to be removed accidentally but which is able to be relatively easily removable by the correct sequence of operations. This therefore provides the ideal sterilisation device providing permanent and completely effective sterilisation but being reversible by a relatively simple surgical procedure.

CLAIMS

1. A sterilisation device comprising a plug which is capable of occluding a fallopian tube;

said plug comprising a generally elongate cylinder said generally elongate cylinder including one or more internal conduit means for entry of one or more suture coils to effect engagement of the plug within the fallopian tube, said suture coils forming a re-entrant loop to effect secure anchoring of the sterilisation device.

2. A sterilisation device as claimed in claim 1 in which said generally cylindrical shape comprises an outer surface and first and second end surfaces.

3. A sterilisation device as claimed in claim 1 or claim 2 in which said plug comprises at least three internal conduit means.

4. A sterilisation device as claimed in claim 3 in which each internal conduit means comprises a shaped passageway with first and second orifices respectively connecting said first end surface with said outer surface.

5. A sterilisation device as claimed in claim 4 in which said passageway connects with said outer surface of said plug at a position nearer to said first end of said plug than said second end.

6. A sterilisation device as claimed in claim 5 in which each said suture comprises a length of surgical wire, said wire having memory characteristics such that when said wire is inserted into said internal conduit means, via said first orifice and passed out of said second orifice, said wire

will form a shaped suture providing fixture means to fix said plug to said fallopian tube.

7. A sterilisation device as claimed in claim 6 in which said plug is also provided at said first end surface with handle means enabling said plug to be gripped by an applicator.

8. A sterilisation device as claimed in any one of the preceding claims in which each said suture means is provided with anchor means at said end of said suture adjacent to said first orifice, said anchor means preventing said suture from being further pulled through said internal conduit means.

9. A sterilisation device as claimed in claim 8 in which said anchor means is shaped to be able to be gripped by extractor tool means to enable each said suture to be removed from said plug thereby enabling said plug to be removed from said fallopian tube to reverse the sterilisation procedure.

10. A sterilisation device as claimed in any of the preceding claims in which each said suture describes a generally circular path on exiting from said second orifice.

11. A sterilisation device as claimed in any one of the preceding claims in which said plug is provided with one or more surface receptor features, each of which is positioned proximate to each second orifice, said surface receptor features being formed to receive the end of a suture to securely locate the said end of each suture.

12. A sterilisation device as claimed in any one of the preceding claims in which the plug may have one or more surface protrusions to effect initial

location of said plug in said fallopian tube prior to engagement of said sutures which effect more permanent engagement.

13. A sterilisation device as claimed in claim 12 in which said surface protrusions comprise external screw thread means to effect positioning of the sterilisation device within said fallopian tube prior to engagement of said suture coils within said fallopian tube.

14. An applicator for insertion of said plug into a fallopian tube, said applicator including means for gripping said handle of said plug to insert said plug into a fallopian tube and including means for moving said one or more sutures through said internal conduit means to emerge from said second orifice to engage with said fallopian tube when said plug is positioned to occlude said fallopian tube.

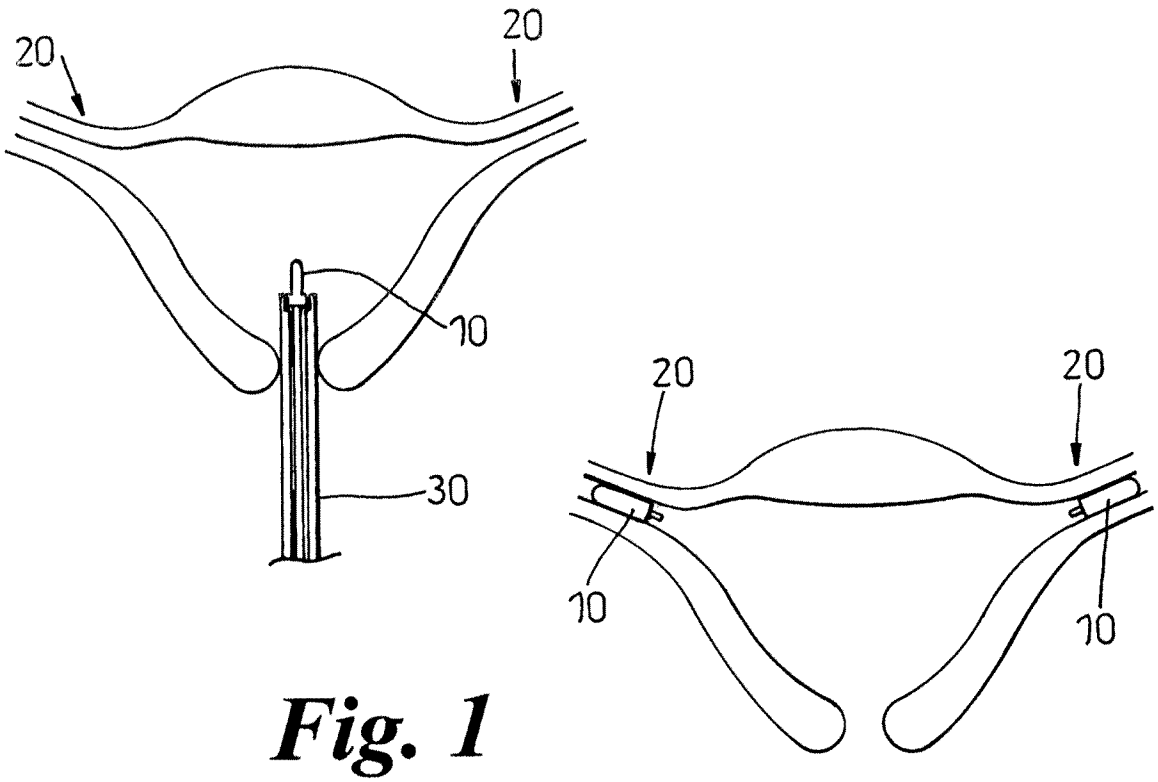
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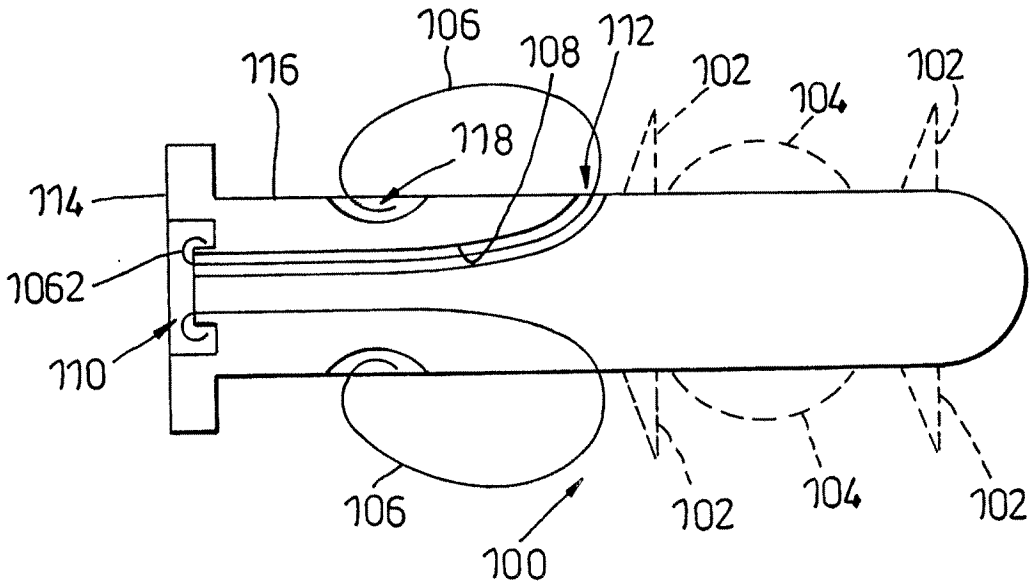
Fig. 1


106
108
112
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102
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102
118
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102
100

Fig. 2

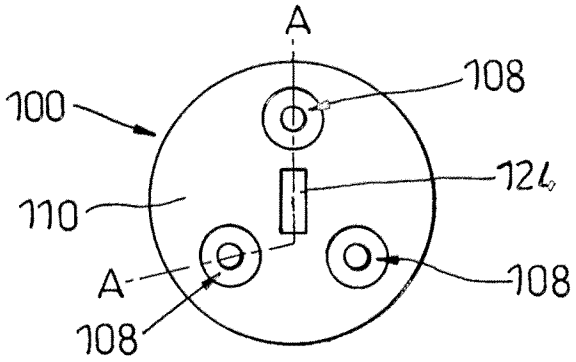

Fig. 3

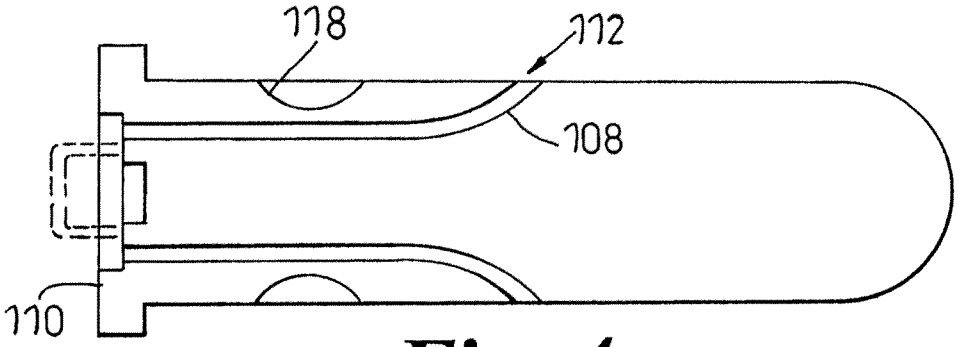

Fig. 4

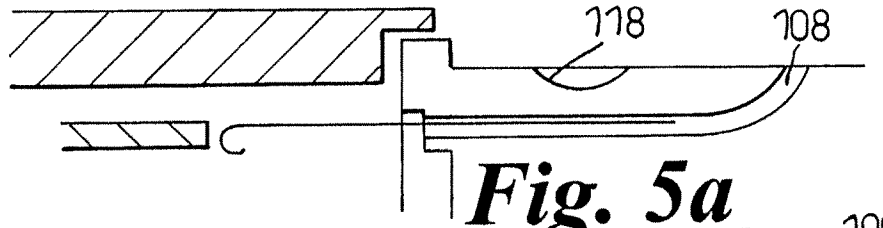

Fig. 5a

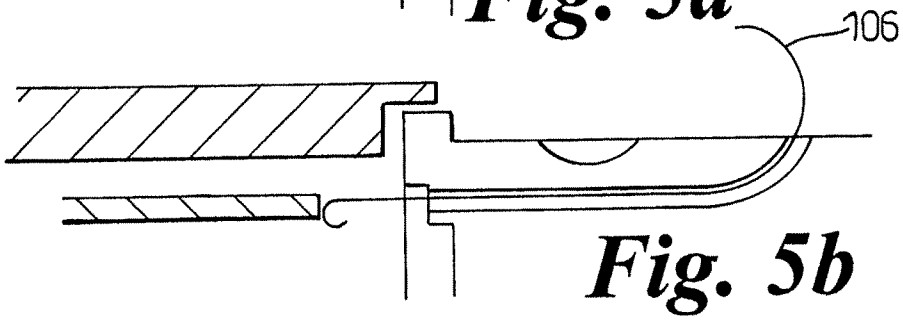

Fig. 5b

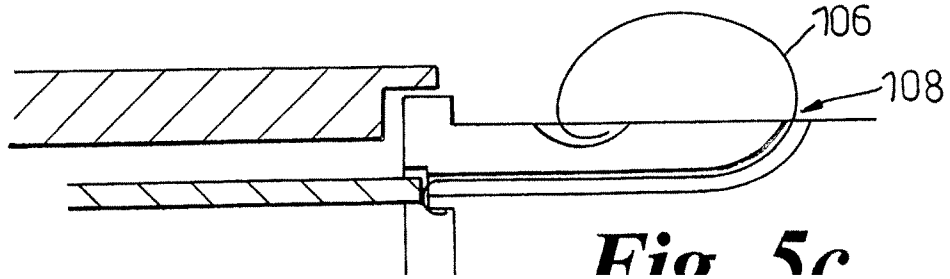

Fig. 5c

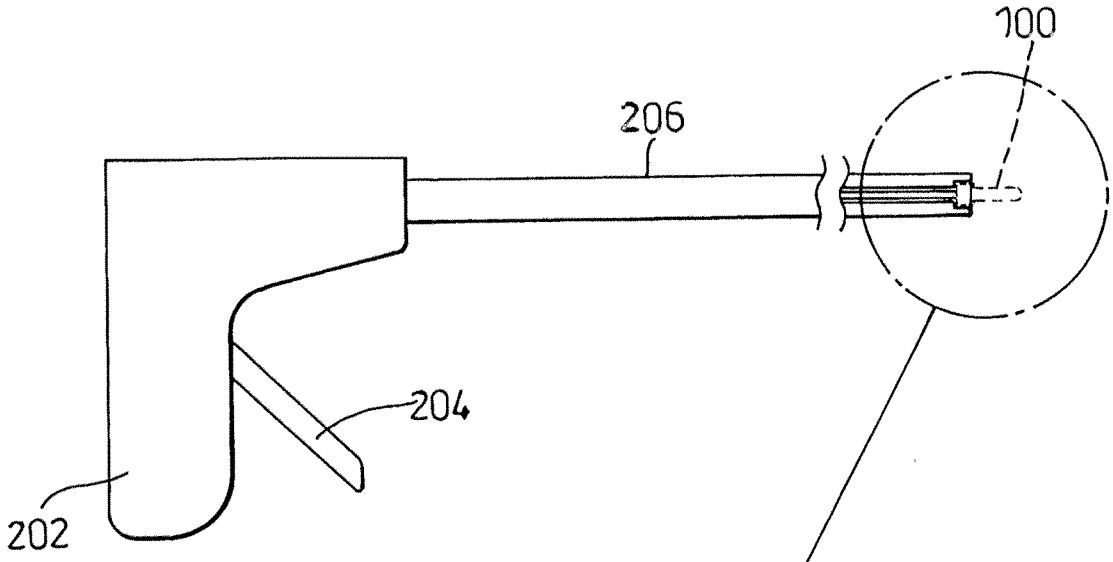

Fig. 6

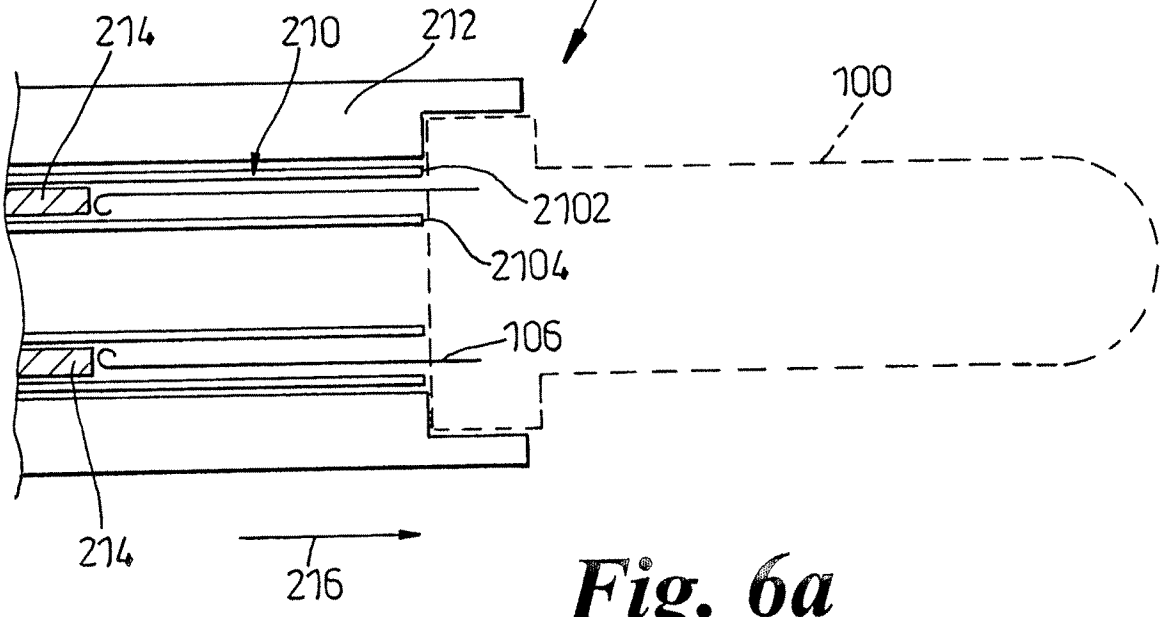

Fig. 6a

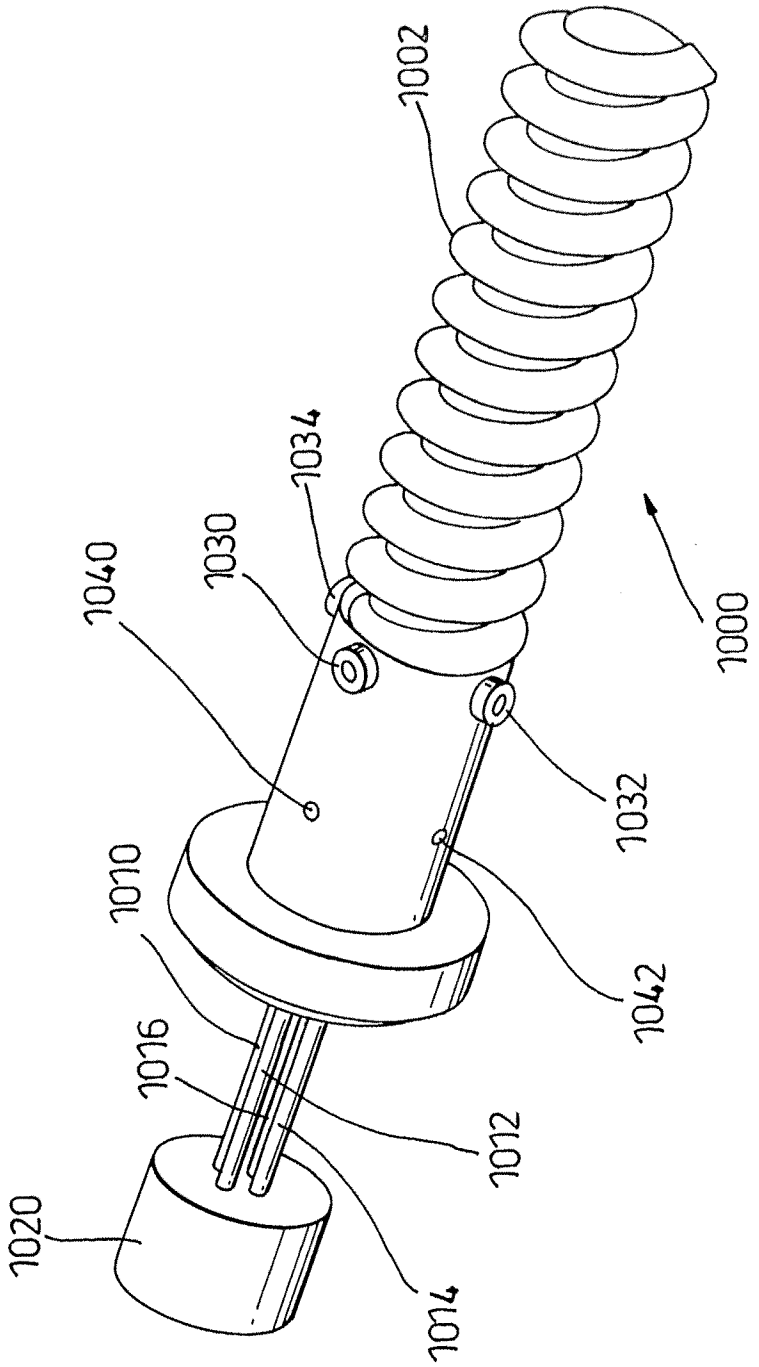

Fig. 7

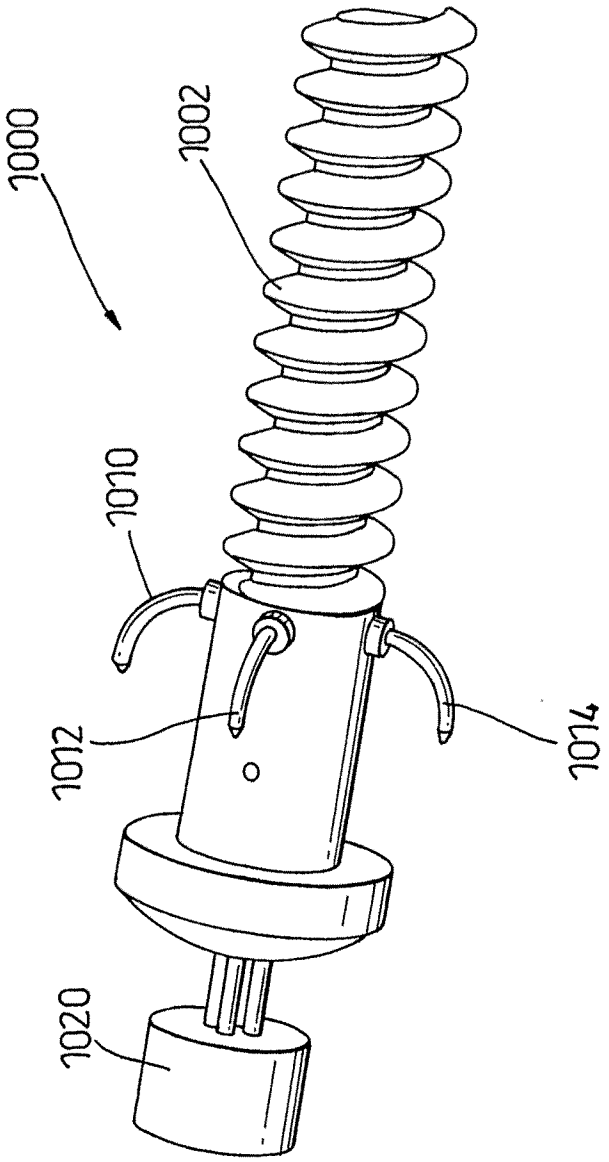

Fig. 8

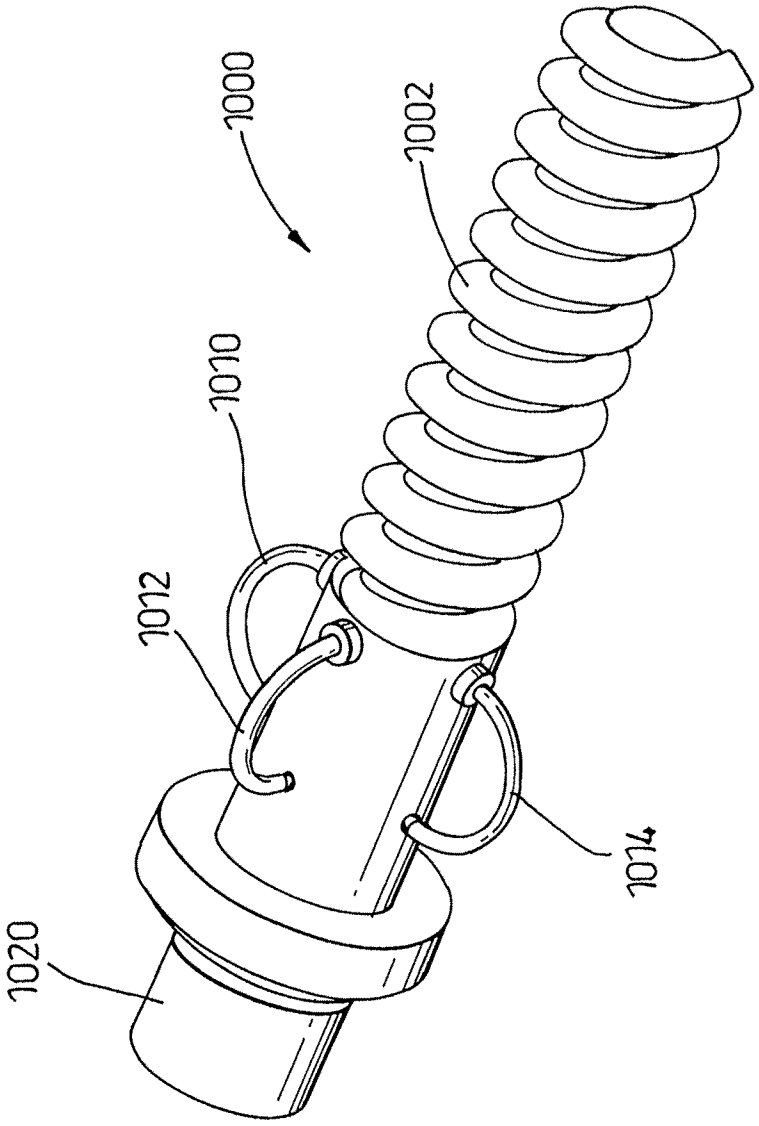

Fig. 9

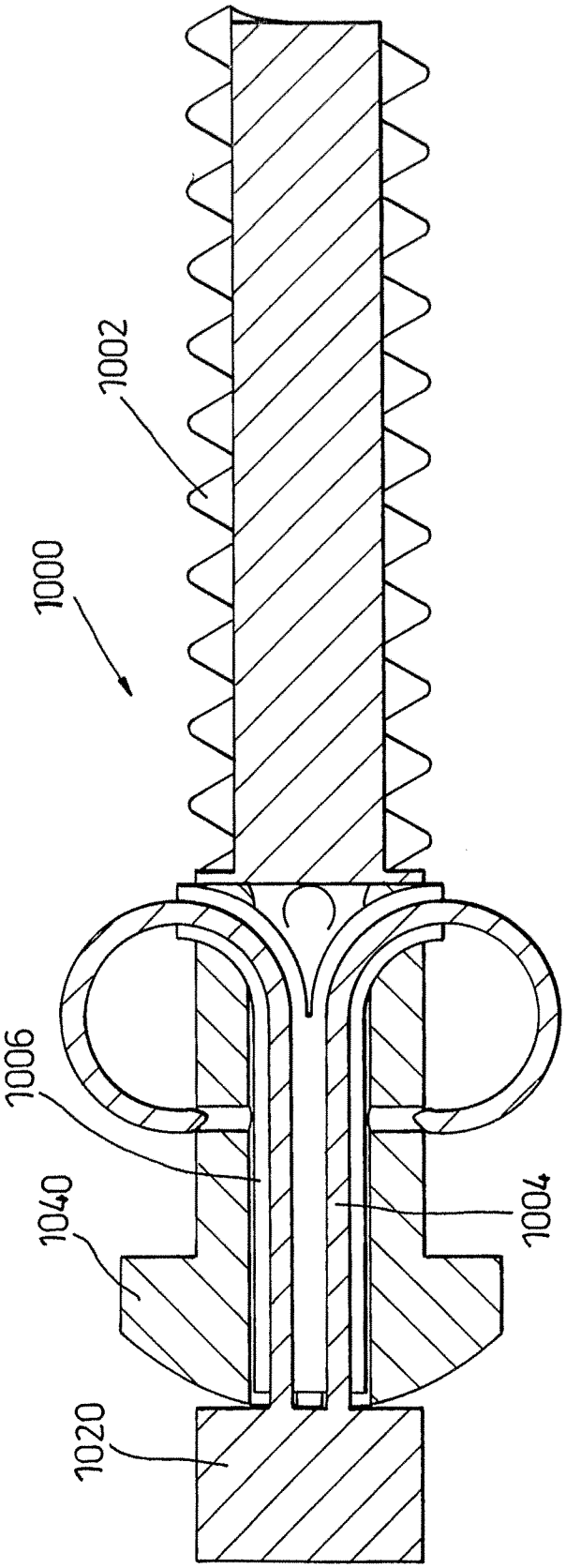

Fig. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/001970

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F6/20 A61F6/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 29 13 036 A (POPP LOTHAR W DR MED) 2 October 1980 (1980-10-02) figures 1,2 page 5, line 2 - page 6, line 4	1,2,4, 6-10,12
Y		3,5,13

Y	US 3 858 571 A (RUDOLPH ARTHUR I) 7 January 1975 (1975-01-07) cited in the application figures 1,2 column 3, line 62 - column 4, line 53	3,5
A		1,4,5, 7-9,12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2004	20. 10. 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Josten, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/001970

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97/12569 A (MAGOS ADAM LASZLO) 10 April 1997 (1997-04-10) cited in the application figures 1-3 page 5, line 9 - line 14 page 5, line 31 - line 36	13
A	GB 2 010 728 A (WOLF GMBH RICHARD) 4 July 1979 (1979-07-04) figure 6	12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2004/001970

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-13

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13

A sterilisation device

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2. claim: 14

An applicator for insertion of a plug into a fallopian tube

INTERNATIONAL SEARCH REPORT

PCT/GB2004/001970

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